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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,863	11/19/1999	INDU PARIKH	401930/SKYEPHARMA	7862

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/443,863	PARIKH ET.AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-52,54-75,77-95,97-104 and 107-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52,54-75,77-95,97-104 and 107-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-1-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 7-22-05 is acknowledged.

Claims included in the prosecution are 50-52, 54-75, 77-95, 97-104, and 107-131.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/07414 cited in the previous action. WO discloses the same process of preparation for the rapidly dispersing oral dosage forms of hydrophobic compounds wherein the particles are coated with at least two surfactants; one of the surfactants is a phospholipid (surface modifying agent). The average particle sizes of the hydrophobic compound are less than 10 microns. The composition contains other claimed materials such as celluloses and mannitol. The process of preparation involves the mixing of the components (water insoluble active agent and the surface modifying agents) in an aqueous medium, sonicating it and lyophilizing the composition to form particles (note the abstract, page 2, line 25 through page 8, line 19, Examples and claims). The process by WO differs from the claimed process in the amended claims in that, the bulking agent is added along with the active agent and the surface modifiers. However, in the paragraph bridging pages 7 and 8, WO teaches subjecting the mixture of the phospholipid and the active agent to procedures such as sonication and homogenization and the goes on to teach that

mannitol and other agents may be added to adjust the final formulation to isotonicity as well as a stabilizing agent during drying. It would have been obvious to one of ordinary skill in the art from these teachings that the addition of mannitol is a manipulatable parameter, that is, it can be added either before or after the homogenization step with the expectation of obtaining the best possible stabilized product. Instant invention therefore, is an obvious extension of the prior art's teachings. A careful review of instant specification on page 6 indicates that mannitol can be added prior to producing the micronized particles of the therapeutic agent (formulation) or to the homogeneous suspension of micro particles prior to freeze-drying and thus, this step does not appear to be critical.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that WO is directed to making submicron-sized particles that do not aggregate upon storage and it neither addresses nor suggests a process of making rapidly dispersible solid dosage forms of a drug. These arguments are not persuasive. The very fact that the prior art teaches that the particles do not aggregate upon storage shows that it recognizes the importance of non-aggregation and therefore, non-aggregation even upon the contact with an aqueous medium is implicit in prior art teachings. Furthermore, as pointed out before, Since the same components will be present, one would expect the same properties upon the addition the addition of an aqueous medium and therefore, the examiner does not find that property surprising. Applicant's arguments that WO is silent with regarding a process in which the bulking/releasing agents are present in amounts described in applicant's presently

claimed invention so as to permit the resulting dried solid suspension, upon reconstitution in an aqueous environment, to revert to a suspension having no more than about 20 % by weight of the particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of the particles comprising a pre-dried suspension. This argument is not persuasive since the amounts of the bulking agent (mannitol) claimed by applicant is 0.1 to 90 % by weight and the amount of mannitol taught by WO in examples appear to fall within this broad range. Applicant's arguments that in WO mannitol is added as an isotonicity adjuster or as a stabilizing aid are not persuasive since irrespective of what it is called, prior art teaches the same component in same amount and therefore, one would expect the same properties.

Upon consideration, the rejection of claims over Yarwood in combination with the secondary references is withdrawn.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,922,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims in the said patent are drawn to a process of preparing microparticles of water insoluble drugs mixing the drug, a phospholipid and another surfactant and applying energy to reduce the particle sizes. Although patented claims do not specifically recite adding the bulking materials such as mannitol, the claims recite 'comprising the steps of' and that applicant's intent to include bulking material such as mannitol in the comprising language is clear from the examples in the said patent which steps are claimed in instant claims. Instant steps of adding the bulking materials thus, is deemed to be included in the patented method claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the disclosure relating to mannitol in 355 patent merely states that this ingredient "may be added to adjust the final formulation to isotonicity as well as a stabilizing aid during drying (col 4, lines 12-14) and that there is no teaching or suggestion provided by the 355 patent to modify the basic method described in this patent so as to arrive at the presently claimed process, which includes combination of steps and amounts of ingredients, which function to allow the achievement of a rapidly dispersible solid dosage form a drug. These arguments are not persuasive. First of all, the patented claims recite, 'comprising. Secondly, steps 1 and 2

in both patent and instant claims are essentially the same. As recognized by applicants themselves, col. 4, lines 12-14 of the patent recite the addition of mannitol during drying. Instant steps 3 and 4 (steps c and d) recite admixing the bulking agent and drying the admixture respectively. Thus, the patented claims together with the language 'comprising' would read on instant claims. With regard to the amounts of mannitol argued by applicant, the examiner points out that instant claims recite a broad range of 0.1 to 90 % and mannitol in 355 patent (55 mg) falls within this range. The rejection is maintained.

5. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,228,399. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims in the said patent are drawn to a process of preparing microparticles of water insoluble drug, cyclosporin by mixing the drug, a phospholipid and another surfactant and applying energy to reduce the particle sizes. Although patented claims do not specifically recite adding the bulking materials such as mannitol, the claims recite 'comprising the steps of' and that applicant's intent to include bulking material such as mannitol in the comprising language is clear from the examples in the said patent which steps are claimed in instant claims. Instant steps of adding the bulking materials thus, is deemed to be included in the patented method claims. Instant generic term, water insoluble drug includes cyclosporine in the patented claims.

Applicant's arguments to this rejection are similar to those put forward for the rejection over 5,922,355 and therefore, the same rationale is deemed applicable.

6. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,465,016u. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims in the said patent are drawn to a process of preparing microparticles of water insoluble drug, cyclosporin by mixing the drug, a phospholipid and another surfactant and applying energy to reduce the particle sizes. Although patented claims do not specifically recite adding the bulking materials such as mannitol, the claims recite 'comprising the steps of' and that applicant's intent to include bulking material such as mannitol in the comprising language is clear from the examples in the said patent which steps are claimed in instant claims. Instant steps of adding the bulking materials thus, is deemed to be included in the patented method claims. Instant generic term, water insoluble drug includes cyclosporine in the patented claims.

Applicant's arguments to this rejection are similar to those put forward for the rejection over 5,922,355 and therefore, the same rationale is deemed applicable.

7. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-44 of copending Application No. 10/443,772. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the claims in the copending application are drawn to fenofibrate compositions and a process of preparation of those compositions involving the same steps as in instant application. Instant generic 'water insoluble drug' is deemed to include fenofibrate in the claims of said copending application.

Applicant's arguments to this rejection are similar to those put forward for the rejection over 5,922,355 and therefore, the same rationale is deemed applicable.

8. Claims 50-52, 54-75, 77-95, 97-104, and 107-131 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-25, 45-47, 52-53, 55-56, 65 and 101-119 of copending Application No. 10/260,788 Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to the same process of preparation and the products resulting from said process and the process is directed to water insoluble drugs. Although the independent claims in said copending application do not recite the addition of bulking materials such as mannitol, the language, 'comprises' provides for the inclusion of such step. Furthermore, the dependent claim 115 in fact recites mannitol. It is obvious therefore, that such a step is included as in instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments to this rejection are similar to those put forward for the rejection over 5,922,355 and therefore, the same rationale is deemed applicable.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK